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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/809,120

03/24/2004

Harry Frederick Bowman

TTI-03

7721

7590

09/29/2008

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EXAMINER

NASSER, ROBERT L

ART UNIT

PAPER NUMBER

3735

MAIL DATE

DELIVERY MODE

09/29/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/809,120	<b>Applicant(s)</b> BOWMAN, HARRY FREDERICK	
	<b>Examiner</b> ROBERT L. NASSER	<b>Art Unit</b> 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3 is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

Applicant's petition to claim priority back to applications 09/733595, 08946366, and 08/106068 has been granted, all of which have the identical disclosure. These applications disclose that one sensor is placed in the vena cava and one in the pulmonary artery. It is the examiner's position that this is one sensor in the venous side and one sensor in the arterial side of the body. As such, it is the examiner's position that claims 1, 2, and 4-9 find support in the prior application and this have a filing date of 8/13/1993. However, claim 3 is not supported in the prior applications, and finds support in the current application, and thus has an effective date of 3/24/2004.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-2 and 4-9 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-53 of U.S. Patent No. 5797398.

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Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are broader versions of the patented claims, which incorporate the venous/arterial distinction in, for example, claim 4. In addition, although the current claims are apparatus claims (1-8), it would have been obvious to use the apparatus for the method it was designed for.

Claims 1-2 and 4-9 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-61 of U.S. Patent No. 5692514. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are broader versions of the patented claims, which incorporate the venous/arterial distinction in, for example, claim 4.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2 and 7-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Alt 5009234. Alt shows a system including a thermal energy source, i.e. a port 6 for introducing a bolus of cool liquid, a first and second temperature sensors 8 and 17 for measuring temperature at different locations in the blood stream of a patient, and a computer 34 that determines cardiac output, which is blood flow, based on the temperature differential (see column 7, lines 25-31). The temperature sensors are not positioned one on the venous side of the heart and one on the arterial side. However, the limitation in question is an intended use limitation and is met if the reference is

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capable of the use. It is the examiner's position that it is possible to position the sensors with one on the venous side and one on the arterial side. Hence, Alt meets the claim language. Claim 2 is rejected in that Alt has the sensors on a catheter that is capable of being introduced either into the venous system or the arterial system.

Claims 7-8 are rejected for the reasons given above.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Alt in view of Khalil 4217910. Khalil teaches that adding heat is an alternative to providing a cooled fluid in thermodilution measurements. Hence, it would have been obvious to modify Alt to use a heater, as it is merely the simple substitution of one known equivalent thermal source for another.

Claim 3 is allowable. Claim 3 defines over the art in that none of the art has two catheters in combination with the features of claim 1. The examiner notes that since both sensors of Alt are in the heart (vena cava and pulmonary artery), the examiner sees no motivation to add a second catheter and have more devices inside the heart.

Claims 4, 5, and 9 would be allowable if the double patenting rejection were overcome.

Claims 4 and 5 define over the art in that none of the art teaches measuring blood flow based on two different temperature differences, as claimed.

Claim 9 defines over the art in that none of the art teaches placing one sensor on the venous side and one sensor on the arterial side and measuring the difference on temperatures, as claimed. Alt teaches placing one sensor in the aorta and one in the left ventricle, neither of which are on the venous side of the circulatory system.

Applicant's arguments filed 9/19/2008 have been fully considered but they are not persuasive.

The terminal disclaimer is invalid in that applicant disclaimed specific claims. This is improper. A terminal disclaimer must disclaim the entire case.

With respect to Alt, applicant has asserted that Alt does not teach computation involving a value not affected by the thermal energy source, as Alt as both sensor positioned downstream of the thermal source. However, as the examiner noted, the limitation is an intended use limitation. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Here, the catheter of Alt could be positioned with the first sensor in the vena cava and the second sensor in the pulmonary artery. As such, it meets the claim language.

Applicant has argued that modifying Alt with Khalil would destroy Alt, as Alt's sensors are affected but the flow of coolant and there is no equivalent in Khalil. However, it is the examiner's position that the purpose is to measure the temperature differential between the two sensors. Khalil presents a different method of performing the measurement.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **ROBERT L. NASSER** whose telephone number is (571)272-4731. The examiner can normally be reached on m-f 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert L. Nasser Jr/  
Primary Examiner  
Art Unit 3735

March 4, 2008